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Appendix F. LapMan 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K023735

Applicant Information:
Xavier Moreels
Managing Director
Medsys S.A.
Rue Chainisse, 39
B-5030 Gembloux.
BELGIUM.

Date Prepared:
October 30, 2002

Proposed Device:
LapMan Laparoscope Manipulator.

Classification:
General and Plastic Surgery
Class II
21 CFR PART 876.1500

Predicate Device:
AESOP 3000 System and accessories. K972699
THE AESOP 3000 is a robotic computer-driven system whose basic function is to hold and position a rigid laparoscope/endoscope under the direct control of a surgeon in the field of endoscopy/laparoscopy surgery. Communication between surgeon and robotic system is ensured by a voice controlled or a wired system.

Device Description:
LapMan is a robotic computer-driven system used by surgeon to hold and position a rigid laparoscope/endoscope. Surgeon orders are transmitted to the robotic system by a radiofrequency Hand Controlled device. It is indicated for use in General surgery (laparoscopic cholecystectomy, laparoscopic Nissen Fundoplication, laparoscopic inguinal hernia repair, laparoscopic gastric banding), Gynaecology (laparoscopic adnexal surgery i.e. ovarian cystectomy, oophorectomy, adnexectomy, salpingectomy, salpingoneostomy, tubal reanastomosis, laparoscopic management of ectopic pregnancy, laparoscopic treatment of endometriosis, laparoscopic myomectomy, laparoscopic hysterectomy, laparoscopic colposuspension) and Urology (laparoscopic prostatectomy).

Statement of intended use:
The LapMan Laparoscope Manipulator System and Accessories is indicated for use in General Surgery, Gynecology, and Urology where a laparoscope/endoscope is incorporated into the surgical procedure. The LapMan is indicated for specific laparoscopic surgical procedures as defined in the Operations Manual and should not be used for any other surgical procedure or purpose.

The LapMan should only be used by qualified medical personnel, such as trained surgeons, gynecologists, urologists, and similarly-trained medical personnel trained in the use of laparoscopic/endoscopic devices.

Comparison of Technological Characteristics:

The existing differences between the Predicate device and LapMan involve a communication system using radiofrequency instead of a voice controlled or wired system. Magnitude and speed of the allowed motions for LapMan are significantly lower than for predicate. This reduces the risk for the patient in cases of unexpected motions. However the volume which can be explored with LapMan remains sufficient for the intended used and indications.

The differences do not affect safety and effectiveness of the device.

Testing:

Performance testing was performed according to the EN 60529:1991 Amendment1:2000 and IEC 601-1 Amendment 1 (1993), IEC 601-1 Amendment 2 (1995). This electrical test has been conducted by PHOENIX TEST-LAB GmbH, Königswinkel, 10 D-32825 Blomberg, Germany.

Performance testing was performed according to the EN 300 220-3 V1.1.1 (2000-09) *Electromagnetic compatibility and Radio spectrum Matters (ERM); Short range devices (SRD); Radio equipment to be used in the 25 MHz to 1000 Mhz frequency range with power levels ranging up to 500 mW; Part 3 : Harmonized EN covering essential requirements of article 3.2 of the R&TTE Directive.* This test has been conducted by PHOENIX TEST-LAB GmbH, Königswinkel, 10 D-32825 Blomberg Germany.

Environmental Testing was conducted according to the following standards:

- IEC 601 (1988), EN 60601
- IEC 601-1 Amendment 1 (1991)
- IEC 601-1 Amendment 2 (1995)
- IEC 601-1-1 (1992)
- IEC 601-1-1 Amendment 1 (1995)
- IEC 601-1-2 (1993)
- IEC 601-2-18 (1996)

Electrical and EMC characteristics of the LapMan have been determined to be in compliance with the following standards by SNCH laboratory:

- EN 60601-1-2: 1993 Radiated disturbances (30 MHz to 1 GHz)
- EN 60601-1-2: 1993 Immunity requirements for medical equipment
- EN 61000-4-2: 1995 Electrostatic discharge
- EN 61000-4-3: 1996 Radiofrequency electromagnetic field AM
- EN 61000-4-8: 1993 Power frequency magnetic field

The LapMan Laparoscope Manipulator System and Accessories intended to be introduced complies with the CE Declaration of Conformity European Directive 93/42/EC Annex VII. Testing was performed by SNCH / SEE-Certification (Testing & Calibration), Rue de la Gare, 11A, L-8325 CAPELLEN LUXEMBOURG without deviation or adaptation to the standards listed above. No differences were found to exist between the LapMan and the applicable standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 7 2003

Medsys, s.a.
c/o Mr. Jeff Morgan
JWM Associates
13723 Dana Lane East
Puyallup, Washington 98373

Re: K023735
Trade/Device Name: The LapMan Laparoscope Manipulator System and Accessories
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: May 12, 2003
Received: May 21, 2003

Dear Mr. Morgan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost
for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Appendix C. Indications for Use Statement

510(k) Number (if known): K023735

Device Name: The LapMan Laparoscope Manipulator System and Accessories

Indications for use:
The LapMan Laparoscope Manipulator System and Accessories is indicated for use in General Surgery, Gynecology, and Urology where a laparoscope/endoscope is incorporated into the surgical procedure. The LapMan is indicated for specific laparoscopic surgical procedures as defined in the Operations Manual and should not be used for any other surgical procedure or purpose.

The LapMan should only be used by qualified medical personnel, such as trained surgeons, gynecologists, urologists, and similarly-trained medical personnel trained in the use of laparoscopic/endoscopic devices.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurence of CDRH, Office of Device Evaulation (ODE)

Prescription Use ✓
(per 21 CFR §801.109)

Over-the-Counter Use _____
(Optional Format 1-2-96)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K023735